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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,808	01/27/2000	BJORN H. LINDQVIST	100084.410	2109

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

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DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/331,808

Applicant(s)

LINDQVIST ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-22,24-29,31,32,34-36,39 and 40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 19-22,24-29,31,32,34-36 and 39-40 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 26.                      6) ☐ Other:

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**DETAILED ACTION**

***Status of Claims***

Claims 19-22, 24-29, 31-32, 34-36 and 39-40 are pending in the application and under consideration.

Claims 1-18, 23, 30, 33 and 37 have been cancelled.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

In view of the cancellation of claim 30 the rejection under 35 U.S.C. 101 no longer applies.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 21-22, 24, 26-28, 31-32, 34-36 and 38-40 under 35 U.S.C. 112, first paragraph, due to lack of enabling disclosure is withdrawn in view of the Fitzgerald declaration of record.

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***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-22, 24-29, 31-32, 34-36 and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as amended, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

***Response to Arguments***

1. Applicants argue that the step by which the population of peptides is specifically associated with DNA is an inherent part of the expression process. That cis-acting proteins have a specific activity that they bind to their own encoding DNA. This binding occurs during the expression process.

In response, applicants' argument is unclear as to how specific association can be inherent in the expression process given no structures of any components of the method. Cf. with Example 4 of page 51 which recites the essential requirement for six His residues for binding to occur, as opposed to the non-His containing plasmids.

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The rejection with respect to the use of the term "amplifiable" is withdrawn with the cancellation of said term.

2. Applicants argue that the term "is derived" from a cis-acting protein no longer appears in the present claims.

In reply, claim 29 still contains the term "derived".

The rejection with respect to the "functionally-equivalent fragment" no longer applies with the cancellation of the terms.

3. The rejection under claim 24 no longer applies in view of applicants' statement.

4. The rejection under claim 26 no longer applies with the amendment to the claim.

5. Applicants argue that with the revision of claim 31, the rejection has been addressed.

In response, the original claim recites for a library, not a non-library DNA.

6. The rejection under claim 33 is moot with the cancellation of this claim.

7. Applicants argue that with the amendment to claim 36, the rejection has been overcome.

In reply, see the rejection of the newly amended claim, **infra**.

8. The rejection under claims 37 and 38 are moot with the cancellation of these claims.

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10. Claims 19 and 20 depend on cancelled claim 11. Since applicants have not addressed this rejection, it is believed that applicants are acquiescing therewith.

The newly amended claims are rejected as follows:

A. Claim 21 is unclear as to the produced population of peptides each specifically associated with **and covalently bound** to the DNA encoding sequence. This is inconsistent with the preamble which recites specific association through covalent binding.

B. Claim 27 is unclear as to how it further limits the method of making the peptide expression library. [Up to will include zero as the lower limit].

C. Claim 31 is confusing as to the DNA being described in terms of the two functional properties. Cf. with the original claim 31 which describes said DNA as being introduced in an expression library.

D. Claim 34 is confusing as to the method of identifying a specific target-binding peptide based on the method of producing a peptide expression library. There is no sequence for the peptide library. This claim comprises two independent process steps of making and using.

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E. Claim 36 is indefinite as to the conditions wherein contacting is effected, especially in the absence of positive showing in the specification.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-22, 24-29, 31-32, 34-36 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al (Virology, 1996) either alone, or in view of Mattheakis et al (US 5,922,545) for reasons set forth in the last Office action.

***Response to Arguments***

Applicants argue that Liu does not suggest a DNA constructs can be made comprising nucleic acids sequences encoding a display moiety together with nucleic acid sequences encoding the cis acting protein. It is further argued that the document does not disclose that the cis acting protein might be useful in the production of display expression libraries.

In reply, attention is drawn to page 158 under the Materials and Methods section up to page 150, col. 1. Liu discloses a method of producing cis-proteins comprising of constructing a plasmid containing a mutated cis-proteins and fragments of the P2A genes which had been amplified by DNA primers as shown in Fig 1. Each of the created plasmid is then transformed into a specific strain (BL21) for the production of the proteins. Liu further discloses, page 160, col. 2 that the A proteins remains covalently joined of the 5'end after cleavage (i.e., cis acting proteins, as claimed). Liu discloses at page 163, Discussion section, that the expressed protein can rejoin its DNA encoding sequence (i.e., a specifically associated DNA encoding cis-protein, as claimed) where joining is by covalent bond to the nick 5' DNA. It is considered that the transformation into a specific strain results in the display and



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expression of the protein. [Note that claim 21 does not recite for any elements by which the peptide expression is displayed].

Applicants argue that Mattheakis relates to polysome libraries. These libraries are argued to link a mRNA molecule with its encoded protein. Applicants further incorporate their comments in the Oct. 9, 2001 amendment. Applicants have attached a review by Dr. Fitzgerald setting out the different types of display libraries and also their uses. Mattheakis is argued as being concerned with polysome technology. It is argued that there is no motivation in the document to change to a system that does not require polysomes.

In response, applicants' argument as to the motivation is unclear. Mattheakis discloses a system in which a DNA binding protein which contains mRNA is displayed and expressed in vitro. Mattheakis is employed for the purpose that it would be obvious to employ Mattheakis method to Liu's cis acting protein. Whether Mattheakis termed his method polysome is immaterial since polysome simply includes mRNA with the DNA binding protein. Applicants' use of the word comprising does not preclude the presence of mRNA with the DNA binding protein. However, Mattheakis method appears to be the same to the instant method as specifically described in the instant Example 4 i.e., in vitro transcription/translation. See also, the Fitzgerald

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declaration of record which recites an in vitro procedure. Furthermore, the declaration states at page 2, paragraph 4 that "substitution of alternative covalent cis-acting DNA binding proteins ....is a matter of routine...."

[Claim 21 would be allowable if claims 24 and 25 or 40 would be incorporated therein].

No claim is allowed.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

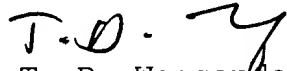
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw  
October 17, 2003